The US Regulatory System for Crops & Foods Improved Through Biotechnology

Crops and foods improved through biotechnology have undergone more rigorous safety reviews, in depth and detail, than any other foods in history.

Complete description of the extensive US regulatory process with details can be found here: http://usbiotechreg.epa.gov/usbiotechreg/ , which has been in place since 1986: http://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf .

The U.S. Regulatory Process Involves comprehensive regulatory oversight by USDA, EPA & FDA.

USDA: Database of regulatory reviews for all transgenic crops cleared for commercial planting here: http://usbiotechreg.epa.gov/usbiotechreg/database_pub.html per regulations found here: http://www.aphis.usda.gov/biotechnology/index.shtml . A comprehensive database of all risk assessments for permission to conduct field trials is here: http://www.nbiap.vt.edu/

FDA requires all foods placed on the market to be safe. Because of this overarching safety requirement, FDA does not require specific reviews of foods derived from crops improved through biotechnology because the process of production tells one nothing about safety. Safety depends on the characteristics of the end product regardless of how it was produced. FDA has prepared a thorough list of points to consider in evaluating and ensuring the safety of "bioengineered foods". Details can be found here: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096095.htm.

Agricultural biotechnology companies are on record requesting the consultation process be made mandatory. Without exception, all "bioengineered" foods on the market have gone through the FDA review process, and these biotech companies are on record they will continue to do this for all such foods. A compilation of summaries on all completed FDA consultations is here: http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=bioListing

FDA staff conduct rigorous internal review of all data provided by companies/product developers. They also subject such data to peer review by multiple invited external experts before confirming to the applicant that all safety questions have been satisfactorily answered.

The system in the European Union (as also Canada, Japan, Australia, New Zealand, and many other countries) is similarly rigorous. Risk assessment research has been extensive, as shown in this from the EU:

Indeed, the use of more precise technology and the greater regulatory scrutiny probably make them even safer than conventional plants and foods; and if there are unforeseen environmental effects - none have appeared as yet - these should be rapidly detected by our monitoring requirements. On the other hand, the benefits of these plants and products for human health and the environment become increasingly clear.

> **--European Commission, Press Release of 8 October 2001, announcing the release of 15 year study including 81 projects/70M euros, 400 teams**
> (http://ec.europa.eu/research/fp5/eag-gmo.html and
> http://ec.europa.eu/research/fp5/pdf/eag-gmo.pdf)

The main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research, and involving more than 500 independent research groups, is that biotechnology, and in particular GMOs, are not per se more risky than conventional plant breeding technologies…

> http://ec.europa.eu/research/biosociety/pdf/a_decade_of_eu-funded_gmo_research.pdf

"…because the technique is so sophisticated, in many ways it is probably safer for you to eat GM products - plants that have been generated through GM - than normal plant foods, if you have any sort of reaction to food, because you can snip out the proteins that cause the negative reaction to certain parts of the population."

> --Sir David King, Chief Science Advisor, UK
> The Guardian Unlimited, 27 November 2007
> http://www.guardian.co.uk/gmdebate/Story/0,,2217712,00.html